

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Konradi et al.	Confirmation No.:	8080
Serial No.:	10/804,950	Art Unit:	1634
Filed:	March 19, 2004	Examiner:	K. Salmon
Customer No.:	21559		
Title:	NUCLEIC ACID MOLECULES THAT ARE DIFFERENTIALLY REGULATED IN A BIPOLAR DISORDER AND USES THEREOF		

PETITION UNDER 37 C.F.R. § 1.181 TO WITHDRAW FINALITY

Applicants hereby petition under 37 C.F.R. § 1.181 that the finality of the rejection of claims 1, 2, and 39-41 in the Office action mailed July 9, 2009 be withdrawn.

*Statement of the facts*

Applicants have discovered that changes in expression of genes encoded by the nuclear genome that code for polypeptides involved in mitochondrial energy metabolism can be used to determine whether a patient has bipolar disorder or a propensity to develop bipolar disorder. Claim 1, the sole independent claim, recites a microarray including such genes and is reproduced below, showing the amendment to this claim made on April 7, 2009.

1. A microarray consisting of ~~a solid support onto which~~ at least two nucleic acid molecules ~~are bound~~, at least 90% of which are either:
  - (a) nucleic acid molecules that encode polypeptides of complex I, II, III, IV, or V of the mitochondrial respiratory chain, said polypeptides being naturally coded for by a nuclear gene, or
  - (b) fragments of the nucleic acid molecules of (a), said fragments being at least 15 nucleotides in length.

The specification (page 18, lines 21-22) defines a “microarray” as an organized collection of at least two nucleic acid molecules or polypeptides affixed to a solid support.

Applicants received an Office action dated July 9, 2009 (“the final action”) in which claim 1 and its dependent claims were finally rejected on two new grounds under 35 U.S.C. § 103(a). The Office also stated Applicants’ claim amendment necessitated these new grounds of rejection.

The first rejection was made over Van den Heuvel et al., *Am. J. Human Genet.* 62:262-268, 1998 (“Van den Heuvel”) in view of U.S. Patent No. 6,040,138 (“Lockhart”). Van den Heuvel is cited as teaching (a) a mutation in the human nuclear gene encoding the AQDQ subunit of the mitochondrial respiratory chain complex I, (b) the cDNA sequence of gene encoding this subunit, (c) that the AQDQ gene is a nuclear gene. Lockhart is cited as teaching placing oligonucleotide probes onto an array to detect expression.

The second rejection was over U.S. Patent Application Publication No. 2006/0099578 (“Wallace”), as evidenced by U.S. Patent No. 5,494,794 (“Wallace ‘794”), in view of three references: Van den Heuvel; Van den Heuvel and Smeitink, *BioEssays* 23:518-523, 2001 (“Smeitink”); and U.S. Patent Application Publication No. 2008/0187911 (“Papaconstantinou”). In this rejection, Wallace is cited as teaching an array consisting of probes for genes from the mitochondrial genome, but is noted as failing to teach an array consisting of only nuclear encoded mitochondrial genes. Van den Heuvel and Smeitink are cited as teaching that (a) relatively few patients having (energy metabolism) deficiencies have defects in mitochondrial genes, and that it would be useful to screen patients for abnormalities in nuclear DNA. Papaconstantinou is cited as teaching microarrays including DNA of only nuclear origin.

#### *Requirement for making an Office action final*

The M.P.E.P. sets forth the criteria for making a rejection final.

Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed

during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

M.P.E.P. § 706.07(a).

The critical issue in determining if a claim amendment “necessitates a new ground of rejection” is whether the rejection could have been made prior to that amendment being entered. Because the rejections set forth in the July 9, 2009 Office action can be applied to claim 1 prior to the April 7, 2009 amendment, this amendment did not necessitate the new grounds for rejection in the final action. Accordingly, it is improper to make this action final. These reasons are detailed below.

#### *Analysis*

Claim 1 was amended on April 7, 2009 to remove language directed to a “solid support.” The term “microarray,” as recited in claim 1, is defined by the specification as including a solid support. As set forth below, none of the rejections in the final action hinges on the explicit recitation of the term “solid support.” Accordingly, each of these rejections could have been presented before the April 7, 2009 claim amendment. Indeed, because the claim scope was not altered by this amendment, any rejection made against claim 1 following the April 7, 2009 amendment could have also been made prior to this amendment.

The first § 103(a) rejection of claim 1 (Van den Heuvel in view of Lockhart) in the final action relies on Van del Heuvel as teaching mutations in a particular nuclear gene encoding a polypeptide of complex I of the mitochondrial respiratory chain and Lockhart as teaching oligonucleotide arrays. This rejection therefore does not hinge on whether claim 1 explicitly recites a “solid support.” The April 7, 2009 claim amendment thus did not necessitate this rejection.

A similar analysis applies to the second § 103(a) rejection (Wallace in view of Van den Heuvel, Smeitink, and Papaconstatinou). Wallace is cited by the Office for teaching an array of genes coded for by the mitochondrial genome, some of which include genes

involved in the mitochondrial respiratory chain. Wallace, however, is silent with respect to nuclear encoded genes of the mitochondrial respiratory chain. Van del Heuvel and Smeitink are each cited as teaching nuclear encoded genes involved in the mitochondrial respiratory chain, and Papaconstantinou is cited as teaching arrays with only nuclear encoded genes. As with the first rejection, the applicability of these references does not hinge on whether or not claim 1 explicitly recites “solid support.” Accordingly, Applicants’ amendment also did not necessitate this rejection.

Finally, because a “microarray” is defined in the specification as including a “solid support,” the April 7, 2009 amendment, which solely removed the term “solid support” and therefore merely corrected a redundancy in the claim language, did not change the scope of claim 1. Because this amendment did not change the claim scope, any rejection that could have been made against amended claim 1 could have also been made against claim 1 prior to the April 7, 2009 amendment. For this reason as well, Applicants’ amendment did not necessitate the new grounds of rejection in the final action.

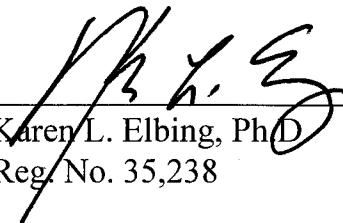
### *Conclusion*

Because the rejections set forth in the final action could have been presented prior to the April 7, 2009 amendment, Applicants’ amendment did not necessitate either of these grounds for rejection. Withdrawal of finality of this rejection is therefore respectfully requested.

Applicants believe that no fees are due at this time. However, if there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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